IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ALLERGAN, INC. *Plaintiff*, v. TEVA PHARMACEUTICALS USA, INC., et al., *Defendants*.	§ § § § § § § § §	Case No. 2:15-CV-1455-WCB

CLAIM CONSTRUCTION MEMORANDUM OPINION AND ORDER

On August 26, 2016, the Court held a hearing to address the proper construction of the disputed terms of the six patents at issue in this case, U.S. Patent Nos. 8,629,111 ("the '111 patent"); 8,633,162 ("the '162 patent"); 8,642,556 ("the '556 patent"); 8,648,048 ("the '048 patent"); 8,685,930 ("the '930 patent"); and 9,248,191 ("the '191 patent"). After considering the arguments made by the parties at the hearing (Dkt. No. 182), in their claim construction briefing (Dkt. Nos. 155, 165, and 171), and in their supplemental claim construction briefs (Dkt. Nos. 190, 211, and 213), the Court issues this order setting forth the Court's construction of the claim terms identified by the parties as being in dispute.

The patents in suit are directed to an emulsion containing cyclosporin, a compound that is useful for treating an ophthalmic condition known variously as "dry eye," "dry eye disease," or "dry eye syndrome," and a related condition known as keratoconjunctivitis sicca.[1] The

[1] Cyclosporin is often spelled cyclosporine, including in many research papers. The patents generally spell the term cyclosporin (with a few inconsistencies). The Court will spell the term as the asserted patents (generally) do. The difference in spelling does not reflect any difference in the designated compound or group of compounds.

patents are mainly directed to the composition of the emulsion containing the cyclosporin component.

All six patents are entitled "Methods of Providing Therapeutic Effects Using Cyclosporin Components." The patents share a common specification, except for a 14-line passage found in the '111 patent, the '048 patent, and the '930 patent that is not found in the other three.[2] The emulsion that is the subject of many of the claims of the patents contains cyclosporin A, water, and castor oil (a hydrophobic component), as well as certain other named constituents. The claims recite that cyclosporin A is present in an amount of about 0.05% by weight of the composition and castor oil is present in an amount of about 1.25% by weight of the composition.

It was known as early as the 1980s that cyclosporin was effective in treating dry eye. See U.S. Patent No. 4,839,342 to Kaswan. By the mid-1990s, it was known that an emulsion consisting of between about 0.05% and about 0.40% by weight of cyclosporin A and between about 0.625% and 5.0% by weight of castor oil, along with certain other components, could be used in direct administration to the eye. See U.S. Pat. No. 5,474,979 to Ding. The claimed improvement described in the group of asserted patents at issue in this case is that at the particular percentages of cyclosporin A and castor oil recited in the claims, the emulsion surprisingly has therapeutic efficacy roughly equal to that of an emulsion having twice the relative concentration of cyclosporin. The low concentration of cyclosporin in the claimed emulsion had the advantage of not resulting in substantial concentrations of cyclosporin in the patient's bloodstream. The claimed emulsion thus avoided triggering the side effects that often accompany treatments employing higher concentrations of cyclosporin.

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[2] That passage is found at column 2, line 65, through column 3, line 11, of the '111 patent; column 2, line 65, through column 3, line 11, of the '048 patent; and column 2, line 64, through column 3, line 10, of the '930 patent.

The claim construction issues that are in dispute fall into eight categories. One claim term that was initially in dispute has been agreed upon by the parties: The parties have agreed that the phrase "substantially no detectable concentration of cyclosporin A" should be construed to mean "a blood concentration under one-tenth nanogram per milliliter." The Court accepts that construction of the term. The remaining terms in dispute are addressed below.

1. dry eye, dry eye disease, dry eye syndrome, and keratoconjunctivitis sicca

The patents use the terms "dry eye," "dry eye disease," and "dry eye syndrome" at different times. The term "dry eye" is used in claims 20, 23, and 25 of the '111 patent and claims 13 and 23 of the '930 patent. The term "dry eye disease" is used in claims 1, 22, and 23 of the '162 patent; claims 1, 11, and 13 of the '556 patent; and claims 1 and 17 of the '191 patent. The term "dry eye syndrome" is used in claims 18 and 21 of the '162 patent. All three terms are used in the common specification of the six patents. See '111 patent, col. 12, line 4 ("dry eye"); id., col. 2, ll. 40, 66, and col. 14, ll. 34, 39, 44, 67 ("dry eye disease"); id., col. 2, ll. 60-61, 64, and col. 5, ll. 14-15, 19, 29-30, and col. 14, line 55 ("dry eye syndrome"). Allergan argues that all three terms refer to the same condition and that the difference in terminology is not significant. Allergan proposes the following definition for "dry eye" and "dry eye disease": "a group of disorders of the tear film, including those caused by reduced tear production or tear evaporation or an imbalance of tear film components associated with clinical signs, ocular discomfort and/or visual symptoms."

The term keratoconjunctivitis sicca ("KCS") is used in claims 21 and 26 of the '111 patent; claims 18, 21, and 22 of the '048 patent; claims 1, 11, 25, and 35 of the '930 patent; and in the portion of the common specification that is found only in the '111, '048, and '930 patents, see '111 patent, col. 2, line 66, and col. 3, ll. 4-5; '048 patent, col. 2, line 66, and col. 3, ll. 4-5;

'930 patent, col. 2, line 65, and col. 3, ll. 3-4. Allergan argues that KCS is a subset of the condition known as dry eye, and that in patients suffering from KCS the symptoms of dry eye are associated with inflammation of the conjunctiva, the tissue that lines the inside of the eyelids. It proposes the following definition for KCS: "a subset of dry eye disease, characterized by inflammation of the conjunctiva and of the cornea, associated with decreased tears."

The defendants offer no competing definitions of these terms. Instead, they argue that the term "KCS" and all three variants of the term "dry eye"—"dry eye," "dry eye disease," and "dry eye syndrome"—are indefinite. The defendants point out that none of those terms are explicitly defined in the common specification, and they argue that the terms have been used in varying ways in the field over time. Accordingly, they contend that none of the terms would convey a well-understood meaning to a person of ordinary skill in the art.

As the defendants point out, medical literature acknowledges that there is "considerable confusion regarding the definition of dry eye." Stephen C. Pflugfelder et al., The Diagnosis and Management of Dry Eye: A Twenty-five-Year Review, 19 Cornea 644 (2000). The defendants' expert, Dr. Andrew F. Calman, said the same thing in his declaration. He stated that "[a] number of different terms have been used by various authors to describe various subgroups of patients with 'dry eye' symptomatology: dry eye, dry eye syndrome, dry eye disease, keratoconjunctivitis sicca (KCS), keratitis sicca, sicca syndrome, sicca complex, Sjogren syndrome, aqueous deficient dry eye, evaporative dry eye, dry eye associated with Meibomian gland dysfunction, and others." Declaration of Andrew F. Calman, Dkt. No. 165-24, at 7. He explained that different authors have used those terms in different ways, and that the terminology in the field "has been murky and inconsistent at best, and self-contradictory at worst." Id. His declaration

cites several authorities that have noted the heterogeneity of dry eye and the variety of tear film abnormalities that are included within the general category of "dry eye." Id. at 8-11.

Allergan responds that despite differences in usage, persons of ordinary skill in the art know the meaning of KCS and "dry eye," including the terms "dry eye disease" and "dry eye syndrome." Allergan's expert, Dr. Robert J. Noecker, stated that "[d]ry eye encompasses a broad group of tear film disorders generally caused by reduced tear production, tear evaporation, or an imbalance in tear film components (leading to decreased tear quality)." Declaration of Robert J. Noecker, M.D. in Support of Plaintiff Allergan's Claim Constructions, Dkt. No. 155-35, ¶ 19, at 7. Dr. Noecker defined KCS as "a disease falling within the broader category of 'dry eye' disease," which is characterized by inflammation of the conjunctiva and cornea "associated with decreased tears and decreased tear quality." Id. ¶ 22, at 9; id. ¶¶ 30-31, at 12-13. He added that although KCS is sometimes colloquially referred to as "dry eye," a person of ordinary skill in the art "would understand that dry eye is a broader category of disorders of the tear film, and that KCS is a subset of dry eye disease or dry eye syndrome." Id. ¶ 30, at 12.

In support of those assertions, Dr. Noecker referred to various resources, including a 2011 publication of the American Academy of Ophthalmology, which defined "dry eye syndrome" as referring to "a group of disorders of the tear film that are due to reduced tear production or excessive tear evaporation that is associated with ocular discomfort and/or visual symptoms and may cause disease of the ocular surface. This group of disorders is usually referred to as dry eye." American Academy of Ophthalmology Cornea/External Disease Panel, Dry Eye Syndrome—Limited Revision 3 (2011). Dr. Noecker also relied on the definition set forth in a 1999 patent, which stated: "Dry eye generally refers to any tear film abnormality, usually with epithelial abnormalities. A specific deficiency of the aqueous component of the tear

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